

# PATENT COOPERATION TREATY

## PCT

### INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY


(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

REC'D 28 NOV 2005

WIPO

PCT

|  |  |  |  |                      |
|--|--|--|--|----------------------|
| Applicant's or agent's file reference<br>DPPC 138435 MJ  |  | <b>FOR FURTHER ACTION</b>  |  | See Form PCT/PEA/416 |
| International application No.<br>PCT/BE2004/000176   |  | International filing date (day/month/year)<br>15.12.2004                   | Priority date (day/month/year)<br>16.12.2003 |                      |
| International Patent Classification (IPC) or national classification and IPC<br>A61K35/78, A61P35/00, A61P15/12, A61P19/10, A61P5/24, A61P9/10   |  |  |  |                      |
| Applicant<br>BIODYNAMICS   |  |  |  |                      |
| <p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 5 sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input type="checkbox"/> sent to the applicant and to the International Bureau a total of sheets, as follows:</p> <p><input type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p>b. <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p> |  |  |  |                      |
| <p>4. This report contains indications relating to the following items:</p> <p><input checked="" type="checkbox"/> Box No. I Basis of the opinion</p> <p><input type="checkbox"/> Box No. II Priority</p> <p><input type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p><input type="checkbox"/> Box No. IV Lack of unity of invention</p> <p><input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p><input type="checkbox"/> Box No. VI Certain documents cited</p> <p><input type="checkbox"/> Box No. VII Certain defects in the international application</p> <p><input checked="" type="checkbox"/> Box No. VIII Certain observations on the international application</p>  |  |  |  |                      |
| Date of submission of the demand<br><br>17.10.2005   |  | Date of completion of this report<br><br>25.11.2005                        |  |                      |
| Name and mailing address of the international preliminary examining authority:<br><br> European Patent Office<br>D-80298 Munich<br>Tel. +49 89 2399 - 0 Tx: 523656 epmu d<br>Fax: +49 89 2399 - 4465  |  | Authorized Officer<br><br>Pilling, S<br><br>Telephone No. +49 89 2399-8461 |  |                      |



**INTERNATIONAL PRELIMINARY REPORT  
ON PATENTABILITY**

International application No.  
PCT/BE2004/000176

---

**Box No. I Basis of the report**

---

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.
- ☐ This report is based on translations from the original language into the following language , which is the language of a translation furnished for the purposes of:
- ☐ international search (under Rules 12.3 and 23.1(b))
  - ☐ publication of the international application (under Rule 12.4)
  - ☐ international preliminary examination (under Rules 55.2 and/or 55.3)
2. With regard to the **elements\*** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

**Description, Pages**

1-18 as originally filed

**Claims, Numbers**

1-30 as originally filed

**Drawings, Sheets**

1/3-3/3 as originally filed

☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing

3. ☐ The amendments have resulted in the cancellation of:
- ☐ the description, pages
  - ☐ the claims, Nos.
  - ☐ the drawings, sheets/figs
  - ☐ the sequence listing *(specify)*:
  - ☐ any table(s) related to sequence listing *(specify)*:
4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
- ☐ the description, pages
  - ☐ the claims, Nos.
  - ☐ the drawings, sheets/figs
  - ☐ the sequence listing *(specify)*:
  - ☐ any table(s) related to sequence listing *(specify)*:

\* If item 4 applies, some or all of these sheets may be marked "superseded."

**INTERNATIONAL PRELIMINARY REPORT  
ON PATENTABILITY**

International application No.  
PCT/BE2004/000176

---

**Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

---

1. Statement

|                               |             |       |
|-------------------------------|-------------|-------|
| Novelty (N)                   | Yes: Claims | 1-30  |
|                               | No: Claims  |       |
| Inventive step (IS)           | Yes: Claims | 1-28  |
|                               | No: Claims  | 29,30 |
| Industrial applicability (IA) | Yes: Claims | 1-30  |
|                               | No: Claims  |       |

2. Citations and explanations (Rule 70.7):

**see separate sheet**

---

**Box No. VIII Certain observations on the international application**

---

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

**see separate sheet**

Re Item V

**Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

The following documents; D1 - D6 are referred to in this communication; this designation results from the order of citation found in the International Search Report (ISR) and will be adhered to in the rest of the procedure. **Reference to the passage(s) cited in respect of each citation in the ISR will be made unless otherwise specified.**

Claims 1 to 18

1. None of the presently available prior art documents disclose the method of present Claim 1. Hence the subject matter of Claims 1 to 18 is new (Article 33(2) PCT).
2. The closest prior art in respect of Claim 1 appears to be either of documents D2 or D3. Each of these documents disclose methods for the production of a hop extract enriched in 8-prenylnaringenin (8-PN) compared to 6-prenylnaringenin (6-PN) comprising an isomerisation step and an extraction. The difference between the subject matter of present Claim 1 and the prior art is that the prior art isomerisation step is carried out using an ethanolic base solution whereas the present method essentially involves "*the presence of water as a solvent*". On the basis of the experimental evidence provided in the present specification (see particularly Table 2), it appears that the use of water as a solvent increases the yield of 8-PN, *i.e.* ratio of  $(8\text{-PN} \times 100\%) / (8\text{-PN} + 6\text{-PN})$ . This finding could not have apparently been predicted on the basis of the presently available prior art documents and appears surprising. Since 8-PN is the main oestrogenic component of hop extracts and is therefore potentially therapeutically useful it appears that this increase in the yield of 8-PN makes an inventive contribution to the medical art. Hence, the subject matter of Claims 1 to 18 is also inventive (Article 33(3) PCT).

Claims 19 to 30

3. Claims 19 to 30 disclose compositions obtainable by the methods of Claim 1 to 18,

*i.e.* hop extracts enriched in 8-prenylnaringenin (8-PN) compared to 6-prenylnaringenin (6-PN). Although document D1 discloses the production of a hop extract comprising 8-PN, the concentration of 6-PN is not disclosed. The Applicant has referred to analytical data (see present Table 2) which would appear to indicate that sufficient 6-PN would be present in the extracts of D1 to result in a ratio of  $(8\text{-PN} \times 100\%) / (8\text{-PN} + 6\text{-PN})$  of less than 50%. Thus the subject matter of Claims 19 to 30 appears to be new (Article 33(2) PCT).

4. Since none of the prior art documents appear to suggest or teach towards the hop extracts of present Claim 19, it appears that the subject matter of Claims 19 to 28 is also inventive (Article 33(3) PCT).
5. With regard to Claims 29 and 30, these claims are directed towards nutritional or cosmetic compositions. Apart from mere formal support in terms of corresponding wording in the description (see page 14 line 30 to page 15 line 3) no actual nutritional or cosmetic compositions or uses are substantiated in the description. Thus, the subject matter of Claims 29 and 30 (provision of nutritional/ cosmetic compositions) has not plausibly been shown to solve any technical problem. Since it is a prerequisite for establishing inventive step to determine if the underlying technical problem has been solved, inventive step cannot be acknowledged in respect of the subject matter of Claims 29 and 30.

#### **Re Item VIII**

#### **Certain observations on the international application**

6. In view of the absence of any actual cosmetic or nutritional uses/compositions disclosed in the present description (see the comments above in the previous paragraph), the subject matter of Claims 29 and 30 is not supported by the description and appears speculative (Article 6 PCT). The present specification only appears to establish therapeutic uses/compositions (rather than nutritional/cosmetic)